

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Martha G. Welch et al. Confirmation No.: 8041  
Application No.: 10/799,941 Art Unit: 1654  
Filed: March 11, 2004 Examiner: J.J. Harle  
Title: NOVEL MULTYPEPTIDE REGIMEN FOR THE TREATMENT OF  
AUTISTIC SPECTRUM, BEHAVIORAL, EMOTIONAL AND  
VISCERAL INFLAMMATION/AUTOIMMUNE DISORDERS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. §1.131**

I, Martha G. Welch, hereby declare as follows:

1. I am a co-inventor of the subject matter claimed in the patent application having U. S. Serial No. 10/799,941.
2. I have been informed that the claims now pending in this application are directed to a pharmaceutical composition comprising a therapeutically effective amount of secretin in synergistic combination with a therapeutically effective amount of oxytocin.
3. I have been informed that pending claims of the '941 application have been rejected by the patent Examiner over Hollander (U.S. Pub. No. 2006/0105939) in view of an on-line NIH news alert ("The Use of Secretin to Treat Autism" Internet document), and further in view of Swain (E. Swain, Pharmaceutical and Medical Packaging News) and PIERCE (PIERCE Technical Resource Sheet TR0043.0 "Protein Stability and Storage").
4. I conceived of the pharmaceutical composition claimed in the '941 application at least prior to August 17, 2001 as evidenced by the experiments and notes included in the laboratory notebooks attached. A redacted copy of relevant lab notebook entries is attached as Exhibit A.
5. I diligently reduced the claimed invention to practice.
6. I hereby declare that all statements made herein of my own knowledge are true and that

all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent in which this declaration is made.

Date: Sept 27, 2007

  
Martha G. Welch, M.D.